



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0449]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Sun Protection Factor Labeling and Testing Requirements for Over-the-Counter Sunscreen Drug Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0717. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

SPF Labeling and Testing Requirements for OTC Sunscreen Products--21 CFR 201.327(a)(1)

and (i), 21 CFR 201.66(c) and (d)

OMB Control Number 0910-0717--Extension

In the *Federal Register* of June 17, 2011 (76 FR 35620), we published a final rule establishing labeling and effectiveness testing requirements for certain OTC sunscreen products containing specified active ingredients without approved applications (2011 sunscreen final rule; § 201.327 (21 CFR 201.327)). In addition to establishing testing requirements, the 2011 sunscreen final rule lifted the delay of implementing the prior 1999 sunscreen final rule (published in the *Federal Register* of May 21, 1999 (64 FR 27666), and stayed in the *Federal Register* of December 31, 2001 (66 FR 67485), from complying with the 1999 Drug Facts labeling final rule (published in the *Federal Register* of March 17, 1999 (64 FR 13254)), in which we amended our regulations governing requirements for human drug products to establish standardized format and content requirements for the labeling of all marketed OTC drug products in part 201 (21 CFR part 201). Specifically, the 1999 Drug Facts labeling final rule added new § 201.66 (21 CFR 201.66) to part 201. Section 201.66 establishes content and format requirements for the Drug Facts portion of OTC drug product labels. We specifically exempted OTC sunscreen products from complying with the 1999 Drug Facts labeling final rule until we lifted the stay of the 1999 sunscreen final rule. The 2011 sunscreen final rule became effective December 17, 2012, for sunscreen products with annual sales of \$25,000 or more and December 17, 2013, for sunscreen products with annual sales of less than \$25,000 when we published an

extension date notice in the *Federal Register* of May 11, 2012 (77 FR 27591) (2012 extension date notice).

SPF Labeling and Testing for OTC Sunscreens Containing Specified Active Ingredients and Marketed Without Approved Applications

In the *Federal Register* of June 17, 2011 (76 FR 35678), we published a 60-day notice requesting public comment on the collection of information regarding SPF labeling and testing requirements for OTC sunscreen products containing specified ingredients and marketed without approved applications (2011 60-day notice). In that notice, we stated that § 201.327(a)(1) requires the principal display panel (PDP) labeling of a sunscreen covered by the 2011 sunscreen final rule to include the SPF value determined by conducting the SPF test outlined in § 201.327(i). Therefore, that provision resulted in an information collection with a third-party disclosure burden for manufacturers of OTC sunscreens covered by the 2011 sunscreen rule. We determined that products need only complete the testing and labeling required by the 2011 sunscreen rule once and then continue to use the resultant labeling (third-party disclosure) going forward without additional burden. This one-time testing would need to be conducted within the first 3 years after publication of the 2011 sunscreen final rule for all OTC sunscreens covered by that rule.

We determined that the third-party disclosure burden by manufacturers of OTC sunscreens covered by the 2011 sunscreen rule was based on: (1) an estimate of the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information; (2) the conduct of SPF testing based on the estimated number of existing formulations; (3) an estimate of the time to relabel currently marketed OTC sunscreens containing specified ingredients and marketed

without approved applications; and (4) testing and labeling of new products introduced each year. The estimate for this burden in the 2011 60-day notice was a total of 30,066 hours in years one and two and a total of 966 in each subsequent year.

All currently marketed OTC sunscreen drug products are already required to comply with the SPF labeling requirements specified by the 2011 sunscreen final rule. However, our original estimate also included the burden of new products introduced each year. We estimated that as many as 60 new OTC sunscreen products stock keeping units (SKUs) may be introduced each year, which must be tested and labeled with the SPF value determined in the test. We estimated that the 60 new sunscreen SKUs represent 39 new formulations. The burden for testing and labeling these formulations was estimated at 30 hours per year.

Drug Facts Labeling for OTC Sunscreens

Because the 2011 sunscreen final rule also lifted the delay of implementing the Drug Facts regulations (§ 201.66) for OTC sunscreens, the rule also modified the information collection associated with § 201.66 (currently approved under OMB control number 0910-0340) and added a third-party disclosure burden resulting from requiring OTC sunscreen products to comply with Drug Facts regulations. In the 1999 Drug Facts labeling final rule, we amended our regulations governing requirements for human drug products to establish standardized format and content requirements for the labeling of all marketed OTC drug products, codified in § 201.66. This section establishes requirements for the Drug Facts portion of labels on OTC drug products requiring such labeling, to include uniform headings and subheadings, presented in a standardized order with minimum standards for type size and other graphical features. Therefore, OTC sunscreen products already on the market at that time incurred a one-time burden to comply with the requirements in § 201.66(c) and (d). In the 60-day notice, the burden

was estimated as 43,200 hours for existing sunscreen SKUs and 720 hours for new sunscreen SKUs.

The compliance dates for the 2011 sunscreen final rule that lifted the delay of the § 201.66 labeling implementation data for OTC sunscreen products were December 17, 2012, for sunscreen products with annual sales of \$25,000 or more and December 17, 2013, for sunscreen products with annual sales of less than \$25,000, respectively, when we published the 2012 extension date notice. All currently marketed sunscreen products are, therefore, already required to comply with the Drug Facts labeling requirements in § 201.66 and will incur no further burden in the 1999 Drug Facts labeling final rule. However, new OTC sunscreen drug products will be subject to a one-time burden to comply with Drug Facts labeling requirements in § 201.66. In the 2011 60-day notice, we estimated that as many as 60 new product SKUs marketed each year must comply with Drug Facts regulations. We estimated that these 60 SKUs would be marketed by 30 manufacturers, which will spend approximately 12 hours on each label based on the most recent estimate used for other OTC drug products to comply with the 1999 Drug Facts labeling final rule, including public comments received on this estimate in 2010 that addressed sunscreens. This is equal to 720 hours annually (60 SKUs, 12 hours per SKU). We stated that we do not expect any OTC sunscreens to apply for exemptions or deferrals of the Drug Facts regulations in § 201.66(e). However, we considered this in 2013 and estimated the burden for an exemption or deferral by considering the number of exemptions or deferrals we have received since publication of the 1999 Drug Facts labeling final rule (one response) and estimating that a request for deferral or exemption would require 24 hours to complete. Multiplying the annual frequency of response (0.125) by the number of hours per response (24) gives a total response time for requesting an exemption or deferral equal to 3 hours.

In the *Federal Register* of August 22, 2018 (83 FR 42509), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Third-Party Disclosure Burden (New Sunscreens)¹

| Activity | No. of Respondents | No. of Disclosures per Respondent | Total Annual Disclosures | Average Burden per Disclosure | Total Hours |
|---|--------------------|-----------------------------------|--------------------------|-------------------------------|-------------|
| Conduct SPF testing in accordance with § 201.327(i) for new sunscreens | 20 | 1.95 | 39 | 24 | 936 |
| Create PDP labeling in accordance with § 201.327(a)(1) for new sunscreen SKUs | 20 | 3 | 60 | 0.5 (30 minutes) | 30 |
| Total | | | | | 966 |

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 2.--Estimated Annual Third-Party Disclosure Burden (Drug Facts Labeling)¹

| Activity | No. of Respondents | No. of Disclosures per Respondent | Total Annual Disclosures | Average Burden per Disclosure | Total Hours |
|---|--------------------|-----------------------------------|--------------------------|-------------------------------|-------------|
| Format labeling in accordance with § 201.66(c) and (d) for new sunscreen SKUs | 20 | 3 | 60 | 12 | 720 |
| Request for Drug Facts exemption or deferral § 201.66(e) | 1 | 0.125 | 0.125 (7 minutes) | 24 | 3 |
| Total | | | | | 723 |

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

We note that these estimates may be adjusted in the future as the result of a detailed analysis of sunscreen market data conducted by FDA as part of the development of an upcoming proposed rule on OTC sunscreen products (RIN 0910-AA01). FDA intends to either or both amend this information collection or seek approval of additional information collections, as appropriate, concurrent with publication of the proposed rule.

Dated: February 4, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

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